



### 13. Special 510k Summary

FOR ELECTRICAL LYMPH AND VENOUS-INSUFFICIENCY SYSTEM  
(IPC-BOOT, model C-9000)

K070324  
Page 1 of 3

Date Prepared: DECEMBER 20, 2006

**1. 510(k) OWNER NAME:**

C-Boot Ltd.  
Kibbutz Yiron, Merom Hagalil, 13855, Israel

**SUBMITTER PERSON NAME:**

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**C-BOOT LTD. U.S AGENT:**

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**2. DEVICE NAME**

**Common/Usual Name:** ICP-Boot

**Proprietary/Trade name:** IPC-Boot

**Classification:** *ICP-Boot* has been classified as **Class II** devices under the following classification names:

Name	Product Code	21 CFR Ref.	Panel
Compressible Limb Sleeve	JOW	870.5800	Cardiovascular

**3. PREDICATE DEVICES**

C-Boot's new device (IPC-Boot) is substantially equivalent to C-Boot™, cleared under 510(k) number: **K041659**



#### 4. DEVICE DESCRIPTION

1K070324  
Page 2 of 3

**Modified Device and change Description:** C-Boot's *IPC-Boot* is actually a very similar version of C-Boot's legally marketed device, cleared under 510(k) number K041659. Similarly to the legally marketed device, it is made of the same materials and has the same design, technology and performances.

The only modification that was made to the predicate device is the addition of external electric pump that can activate the device electrically when the patient is immobile. This modification provides a solution for such patients.

The patient may choose whether the device will be used mechanically (self powered), by walking (as the original device) or electrically as the modified new device: *IPC-Boot*, when patient is immobile.

The *IPC-Boot* is a wearable pneumatic compression technology embodied in a therapeutic boot that has the potential to increase treatment efficacy and improve the quality of life for peripheral vascular and lymph disorders patients.

The *IPC-Boot* contains boot legging with inflatable sleeves from the patient's foot up to the knee. The *IPC-Boot* uses an external electric pump. The pump is generated the air to inflate the sleeves through the control system for producing intermittent compression to the lower limb.

C-Boot's solution integrates the technological advantages of dynamic compression pumps that enable preset sequential pressure control which is identical to the pressure level of the pre-amended device (predicate).

This enables the patient to individualize treatment regimes, with the mobility benefit of static compression stockings that activate the calf muscle pump and strengthened the body's natural tendency to enhance lymphatic and venous return.

The modified device covers both self-powered and electrical compression devices and creates one integrated device.



K070324  
Page 3 of 3

## 5. INTENDED USE

The IPC-Boot is a prescriptive device that induces controlled compression of the calf, the foot or a combined compression of both.

The IPC-Boot is intended to assist patients, suffering from lymphatic or venous disorders, by treating many conditions including:

1. Prevention of deep vein thrombosis (DVT)
2. Enhancement of blood circulation
3. Reduction of post-operative pain and swelling
4. Reduction of wound-healing time
5. Stasis dermatitis
6. Treatment and assist healing of cutaneous ulceration
7. Venous stasis ulcers
8. Leg ulcers
9. Chronic venous insufficiencies
10. Reduction of edema
11. Prevent pooling of fluids in limbs
12. Lymphedema

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

*C-Boot's amended device (IPC-Boot)* is substantially equivalent to C-Boot's conventional legally marketed device (C-Boot<sup>TM</sup>), cleared under 510(k) number K041659. C-Boot's new and predicate devices have the same indication for use, same basic shape, characteristics, materials, manufacturing technology and design.

The modified device differs from the predicate device only in the addition of energy source, i.e., the electric pump, transformer and hose.

This modification does not affecting the device's intended use and does not alter the device's fundamental scientific technology.

New device verification and validation tests showed that it is as safe and as effective as the predicate device.

## 7. NONE CLINICAL PERFORMANCE DATA

Tests results are supporting all labeling claims and substantial equivalency.

The modified device was tested with accordance to C-Boot's legally marketed device specification and all acceptance criteria were met.

## 8. CONCLUSIONS

The evaluation of C-Boot's IPC-Boot non-clinical tests demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate device (thanks to the electrical operation addition). Therefore, we believe it is substantially equivalent to C-Boot's legally marketed device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

C-BOOT LTD  
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Carmiel  
Israel 21691  
ATTN: Avi Abraham

**MAY - 3 2007**

Re: K070324

Trade/Device Name: IPC-Boot Model C-9000  
Regulation Number: 21 CFR 870.5800  
Regulation Name: Compressible Limb Sleeve  
Regulatory Class: Class II  
Product Code: JOW  
Dated: March 19, 2007  
Received: April 3, 2007

Dear Avi Abraham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

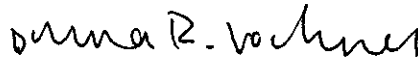
Mr. Avi Abraham - Page 2

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



#### 4. Indication For Use Statement

510(k) Number (if known): K070324

**Device Name:** Electrical Lymph and Venous-Insufficiency System (IPC-Boot)

**Indications for Use:** The IPC-Boot is a prescriptive device that induces controlled compression of the calf, the foot or a combined compression of both.

The IPC-Boot is intended to assist patients, suffering from lymphatic or venous disorders, by treating many conditions including:

1. Prevention of deep vein thrombosis (DVT)
2. Enhancement of blood circulation
3. Reduction of post-operative pain and swelling
4. Reduction of wound-healing time
5. Stasis dermatitis
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7. Venous stasis ulcers
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10. Reduction of edema
11. Prevent pooling of fluids in limbs
12. Lymphedema

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

*Dennis R. Vachon*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K070324